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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,769	09/22/1999	ERIK HELMERHORST	28594/35007A	3787

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/400,769

Applicant(s)

HELMERHORST ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 16, 17, 20-25 and 32-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 32-47 is/are allowed.
- 6) ☐ Claim(s) 1-10, 16-17, 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed February 25, 2004 on July 1, 2004 is acknowledged.

Claim Disposition

2. Claim 1 has been amended. Claims 11-15, 18-19 and 26-31 have been cancelled. Claims 1-10, 16-17, 20-25 and 32-47 are pending and are under examination.
3. The following grounds of rejection are or remain applicable:

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 and 20-25 remain rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 1 and the dependent claims hereto remain indefinite because the claim recites "a method for treating a patient suffering from one or more insulin related ailments selected from the group consisting of hyperglycemia, including hyperglycemia associated with diabetes mellitus, and Alzheimer's disease" and "Alzheimer's disease is not an insulin related ailment per se. The specification on page 26 states that insulin related ailments include ailments which are related to decreased secretion of insulin, decreased responsiveness of cells to insulin or increased secretion of insulin and may

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for example include ailments such as diabetes mellitus (DM), insulinomas, insulin and hypoglycemic drug over dose, gastric dumping syndrome and congenital hyperinsulinism. Other ailments will be known to those of ordinary skill in the field. For example, insulin and glucose therapy leads to improved cognition in Alzheimer's disease patients". The specification does not definitely identify Alzheimer's disease as an insulin related ailment. Further, the prior art found an association between the onset of HNKC (hyperosmolar nonketotic coma) and the prolonged glucocorticoid hypersecretion under stress conditions that exist in DM when accompanied by Alzheimer's disease, as administration of conventional insulin therapy allowed patients to regain consciousness (see Azami et al., Journal of the Japan Diabetes Society, vol. 42, no. 6, pages 461-465, 1999). Thus, Alzheimer's disease is not recognized in the art as a insulin related ailment.

Claim 1 as amended now recites "including hyperglycemia associated with diabetes mellitus", this language is indefinite because "including" is open language and the claim recites "consisting of" which is closed.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1 and 16-17 remain rejected under 35 U.S.C. 102(a) as being anticipated by Sportsman et al. (U.S. Patent No. 5,851,988, December 22, 1998).

Sportsman et al. teach a method for controlling and managing diabetes mellitus with an insulin agonist (non-peptidyl compound that has ionic and hydrophobic chemical moieties spatially located so as to mimic insulin (see claim 1 of the instant application and compounds such as Fig 2A of the reference which has hydrophobic and ionic moieties). As the reference teaches a compound that mimics insulin with one or more ionic residues and hydrophobic residues claims 2 and 3 are anticipated (see abstract, figures 2, 3, 5 and 9, and columns 1-3). The methods of claims 16 and 17 are anticipated because the reference describes methods in columns 2-3, to design and synthesize a molecule that exhibits agonist activity or insulin agonist stimulating activity with respect to the insulin receptor comprising assessing the structural features which correlate with such said activities and doing a comparison study, and to screen candidate compounds for the ability to activate the insulin receptor. Thus, the limitations of the claims are met by this reference.

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7. Claims 1 and 16-17 remain rejected under 35 U.S.C. 102(e) as being anticipated by Sportsman et al. (U.S. Patent No. 6,329,431, August 21, 1997).

Sportsman et al. teach a method for controlling and managing diabetes mellitus with an insulin agonist (non-peptidyl compound that has ionic and hydrophobic chemical moieties spatially located so as to mimic insulin (see claim 1 of the instant application and compounds such as Fig 2A of the reference which has hydrophobic and ionic moieties). As the reference teaches a compound that mimics insulin with one or more ionic residues and hydrophobic residues claims 2 and 3 are anticipated (see abstract, figures 2, 3, 5 and 9, and columns 1-3). The methods of claims 16 and 17 are anticipated because the reference describes methods in columns 2-3, to design and synthesize a molecule that exhibits agonist activity or insulin agonist stimulating activity with respect to the insulin receptor comprising assessing the structural features which correlate with such said activities and doing a comparison study, and to screen candidate compounds for the ability to activate the insulin receptor. Thus, the limitations of the claims are met by this reference.

8. Applicant's arguments filed on July 1, 2004 have been fully considered. Regarding the rejections under 35 U.S.C. 112, first and second paragraphs, the rejection remains. Applicant on page 19 state that page 26, lines 6-12 identifies Alzheimer's as an insulin-related ailment in disclosing that "other ailments include Alzheimer's disease". This argument is not convincing as the specification provides no support for applicant's statements. The specification on page 26 disclose that insulin and glucose therapy leads to improved cognition in Alzheimer's patients, which indicates that the insulin therapy can have a positive effect on the disease, however,

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does not state that Alzheimer's is an insulin related ailment. Thus, the instant specification does not label Alzheimer's disease as an insulin related ailment as stated in the claim, it only indicates that the skilled artisan is aware that cognition improved with insulin therapy for Alzheimer's patients, thus not an insulin related ailment *per se*. In addition a new ground of rejection has been instituted based on applicant's amendments to the claims.

Note that the art rejections of record remains. Applicant on page 20 state that Sportsman does not disclose compounds that possess one or more ionic or hydrophobic amino acid residues of insulin. This statement is inaccurate applicant is directed to for example the compound listed as Fig. 2A which has an ionic group and hydrophobic group on the compound (see both the '988 and '431 patents). It is also stated that Sportsman discloses that the compounds interact with a site located on the kinase portion of the insulin receptor. However, Sportsman teach that their invention is directed to methods to modulate the kinase activity of the insulin receptor or kinase portion thereof; to potentiate insulin activation of the insulin receptor; to potentiate glucose uptake stimulation by insulin; to lower blood glucose and to stimulate glucose uptake *per se* in cells by use of compounds such as Fig 2A (see column 2 of '988 patent, for example). Thus applicant only described a part of the patented invention. Column 4 states that the invention is directed to methods to regulate and manage subjects with diabetes by virtue of administering compounds (insulin agonist), which affect the activity of the insulin receptor ('988 patent, for example).

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It is noted that on page 20 applicant admits that the prior art of record teach "insulin agonist", however, indicates that the references are not relevant. Note that claim 1 recites, "said compound is an insulin agonist". Applicant also states that the compounds taught by the references may have both ionic and hydrophobic moieties, however are not spatially located to mimic insulin as the claimed compound is designed to bind to the insulin binding site of the insulin receptor. According to the references of record, the referenced compound potentiate insulin activation of the insulin receptor, thus it appears that the referenced compound interacts with the insulin-binding site of the insulin receptor. Thus the rejections remain.

Conclusion

9. Claims 32-47 are free of the prior art.

10. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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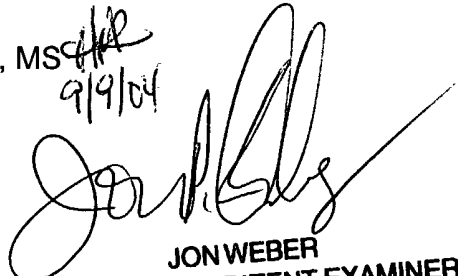
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope A. Robinson, MS
Patent Examiner


JON WEBER
SUPERVISORY PATENT EXAMINER